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89 JUN 21 A10 :41

June 15, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, RM 1061  
Rockville, MD 20852

RE: Docket # 99D-0557

Dear Sir or Madam:

The Food and Drug Administration (FDA) issued guidelines on April 6, 1999 which instituted a de facto ban on non-human primate xenografts because they would expose patients and the public to "significant infectious disease risk".

However, the guidelines failed to address dangers posed by xenografts from other species. Transgenic pigs are considered the source animals of choice for xenotransplants despite the existence of over 25 diseases in pigs that can infect humans. Pigs are not safer than non-human primates. Witness swine influenza, the Porcine Endogenous Retroviruses, paramyxovirus and the new "Nipah" virus in Malaysia which infected over 250 humans, killed 103 and led to the slaughter of some one million pigs.

There are safer, more cost effective and humane alternatives to xenotransplantation that are not being explored by regulatory authorities. These include investing heavily in preventive medicine programs to reduce the need for transplants of all kinds and increase the pool of human organ donors as many European countries have done through legislative schemes.

In addition, substantial tax dollars are being used to develop xenotransplantation with virtually no public debate. Finally, I believe that the FDA violated the Environmental Policy Act by failing to perform an environmental impact statement before allowing clinical xenotransplant experiments.

I respectfully demand that the Department of Health and Human Services ban xenotransplantation from all non-human species immediately.

Sincerely:

  
99D-0557

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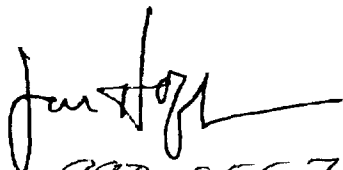
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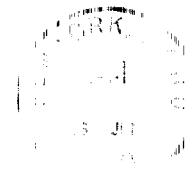
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Bethesda, MD 20852

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